RECORD AND BRIEFS

Nos. 09-958, 09-1158, and 10-238

In the Supreme Court of the United States

TOBY DOUGLAS, DIRECTOR OF THE DEPARTMENT OF HEALTH CARE SERVICES, STATE OF CALIFORNIA,
v.
INDEPENDENT LIVING CENTER OF SOUTHERN CALIFORNIA, INC., ET AL.

Supreme Court, U.S.
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TOBY DOUGLAS, DIRECTOR OF THE DEPARTMENT OF HEALTH CARE SERVICES, STATE OF CALIFORNIA, ET AL.
v.
CALIFORNIA PHARMACISTS ASSOCIATION, ET AL.

TOBY DOUGLAS, DIRECTOR OF THE DEPARTMENT OF HEALTH CARE SERVICES, STATE OF CALIFORNIA,
v.
SANTA ROSA MEMORIAL HOSPITAL, ET AL.

ON WRITS OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE NINTH CIRCUIT

BRIEF FOR THE AMERICAN HEALTH CARE ASSOCIATION, AMERICAN HOSPITAL ASSOCIATION, ASSOCIATION OF AMERICAN MEDICAL COLLEGES, CATHOLIC HEALTH ASSOCIATION OF THE UNITED STATES, FEDERATION OF AMERICAN HOSPITALS, NATIONAL ASSOCIATION OF CHILDREN'S HOSPITALS, NATIONAL ASSOCIATION OF COMMUNITY HEALTH CENTERS, NATIONAL ASSOCIATION OF PUBLIC HOSPITALS AND HEALTH SYSTEMS, NATIONAL COUNCIL FOR COMMUNITY BEHAVIORAL HEALTHCARE, AND SAFETY NET HOSPITALS FOR PHARMACEUTICAL ACCESS AS AMICI CURIAE IN SUPPORT OF RESPONDENTS

CHARLES A. LUBAND
DAVID Z. GROSS
ROPES & GRAY LLP
1211 Avenue of the Americas
New York, N.Y. 10036

MATTHEW B. ARNOULD
ROPES & GRAY LLP
Prudential Tower
800 Boylston Street
Boston, MA 02199

DOUGLAS HALLWARD-DRIEMEIER
Counsel of Record
LARRY S. GAGE
BARBARA D. EYMAN
ROPES & GRAY LLP
One Metro Center
700 12th Street, N.W., Suite 900
Washington, D.C. 20005
(202) 508-4600
Douglas.Hallward-Driemeier@ropesgray.com

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Additional Counsel:

MELINA REID HATTON
MAUREEN D. MUDRON
American Hospital Association
325 Seventh Street, N.W.
Suite 700
Washington, D.C. 20001
(202) 638-1100

JEFFREY G. MICKLOS
Federation of American Hospitals
801 Pennsylvania Avenue, N.W.
Suite 245
Washington, D.C. 20004
(202) 624-1521

DONNA D. FRAICHE
Counsel to the American Hospital Association
Baker, Donelson, Bearman, Caldwell, & Berkowitz, P.C.
201 St. Charles Avenue
Suite 3600
New Orleans, LA 70170
(504) 566-5201

ROGER SCHWARTZ
National Association of Community Health Centers
1400 Eye Street, N.W.
Suite 910
Washington, DC 2005
(202) 296-3900

IVY BAER
KAREN FISHER
Association of American Medical Colleges
2450 N Street, N.W.
Washington, D.C. 20037
(202) 828-0499

TAMARA L. SELTZER
Counsel to the National Council for Community Behavioral Healthcare
Progressive Policy Solutions
1112 Lamont St, NW
Washington, DC 20010
(202) 257-9084

LISA GILDEN
The Catholic Health Association of the United States
1875 Eye Street, N.W., Suite 1000
Washington, D.C. 20006
(202) 296-3993

WILLIAM H. VON OEHSEN
MAUREEN TESTONI
Safety Net Hospitals for Pharmaceutical Access
1501 M Street, NW
Washington, DC 20005
202-552-5859

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INTEREST OF AMICI[1]

Amici are the American Health Care Association, the American Hospital Association, the Association of American Medical Colleges, the Catholic Health Association of the United States, the Federation of American Hospitals, the National Association of Children's Hospitals, the National Association of Community Health Centers, the National Association of Public Hospitals and Health Systems, the National Council for Community Behavioral Healthcare, and Safety Net Hospitals for Pharmaceutical Access.[2] Amici include associations and networks of hospitals, health systems, and other healthcare providers and collectively represent over 20,000 facilities, in addition to more than one hundred thousand individual practitioners, who supply critically needed medical services to millions of Americans throughout the nation. Amici share a strong interest in the proper administration and enforcement of the statutory requirements of the Medicaid Act.

As Medicaid providers, members of our organizations are acutely aware of the difficulties Medicaid recipients face when seeking primary, secondary, and tertiary care. Despite a continued commitment to treating the Medicaid population, increased Medicaid volume at

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[1] The parties have consented to the filing of this brief in letters on file with the Clerk. No counsel for any party authored this brief in whole or in part, and no person or entity, other than amici curiae, their members, or their counsel, made a monetary contribution intended to fund the preparation or submission of this brief.

[2] A short description of each of the amici organizations is included in an appendix hereto.

reduced rates threatens our organizations' members' long-term financial viability and ability to adequately serve Medicaid recipients.

The Supremacy Clause of the Constitution plays a critical part in the system of structural federalism adopted by the Founders. Provider suits such as those brought by respondents vindicate the primacy of federal law by ensuring that the Medicaid Act is not undermined or subverted by conflicting state law, and that the Medicaid program serves Congress's purpose of providing meaningful benefits to Medicaid recipients. Accordingly, amici curiae and their members have a substantial interest in the important issues raised in these cases.

INTRODUCTION AND SUMMARY

Petitioners ask the Court to hold that Medicaid providers are powerless to stop California from enforcing against them drastic cuts in Medicaid payment rates that violate the mandates of federal law. As these cases come to the Court, it is taken as a given that California's indiscriminate, across-the-board 10% cut in rates, without any consideration of the impact of those cuts on beneficiaries' access to care, violates the Medicaid Act. It is also established that respondents, Medicaid providers, are directly and substantially injured by these cuts, which further reduce payment rates that are, for many providers, already significantly below the cost of providing care. Finally, it is established that the administrative review process is singularly ineffective at vindicating the supremacy of federal law. In fact, petitioners have essentially disregarded the administrative process for more than two years, and simply ignored the federal oversight agency when it rejected

California's plan amendment as unsupported by any evidence. Petitioners nonetheless contend that, even assuming all of this, Medicaid providers have no cause of action under the Supremacy Clause to seek a declaration that the cuts are invalid and an injunction preventing their enforcement against providers. Petitioners are wrong.

1. The Medicaid program is responsible for providing access to medical care for more than a quarter of the population of the United States and one third of all children, a percentage that is likely to grow even higher. One of the central requirements of any state Medicaid program is that the program must ensure access for beneficiaries to medical services equal to the access enjoyed by the general population.

Dramatic, indiscriminate cuts of the type at issue in these cases pose a serious threat to an already overtaxed safety net for our most vulnerable citizens, including millions of seniors, children, pregnant women and people with disabilities. Hospitals and nursing homes already are paid by Medicaid programs at rates far below their costs. Hospitals, on average, are compensated at rates 15% less than their costs, and nursing home facilities, on average, are paid at rates almost 10% below provider costs. As a result, providers have been forced to forgo new initiatives and in some cases cease providing certain services. Low reimbursement rates have caused large numbers of doctors to withdraw from the program, with adverse consequences for the entire safety net. It has, for example, become increasingly difficult for Medicaid beneficiaries to find a physician, especially a specialist. Medicaid beneficiaries have difficulty obtaining specialty consultations at an alarming rate, roughly three times more often than

insured patients. And, as access to physicians becomes more difficult, patients turn to hospital emergency departments, an inefficient use of resources that only adds additional pressure to an already over-taxed system.

Multiple courts of appeals have held that across-the-board rate cuts, adopted for purely budgetary reasons and without considering their effect on quality, efficiency, or the availability of care for beneficiaries, are precluded by the Medicaid Act. Lawsuits brought under the Supremacy Clause are the only effective way to prevent states from implementing illegal rate cuts.

The system of administrative oversight by the Department of Health and Human Services ("HHS") is, by constrast, structurally incapable of preventing states from acting in derogation of Medicaid's equal access requirement. Limited to what information the state provides it, HHS is ill-equipped to serve as an independent check against violations of the federal mandate. Nor, when a violation is identified, does HHS have an effective way to bring the state into compliance. The present case, in which petitioners simply ignored the federal administrative proceeding, and continued to implement California's rate cuts even after the proposed state plan amendment was rejected, demonstrates the inadequacy of the administrative scheme.

Without the ability to bring a suit for declaratory and injunctive relief under the Supremacy Clause, respondents would have no avenue for relief, but would instead simply have to endure California's illegal rate cuts.

2. This Court has repeatedly recognized that "the availability of prospective relief of the sort awarded in

Ex parte Young gives life to the Supremacy Clause. Remedies designed to end a continuing violation of federal law are necessary to vindicate the federal interest in assuring the supremacy of that law." *Green* v. *Mansour*, 474 U.S. 64, 68 (1985). Petitioners acknowledge the numerous cases in which this Court has entertained a Supremacy Clause challenge and do not genuinely dispute that there are many circumstances in which such a cause of action exists. *See* Pet. Br. 42-44. Petitioners spend most of their brief arguing instead that such a cause of action should not be recognized in the specific context of a suit to set aside a state law that is invalid because it conflicts with 42 U.S.C. 1396a(a)(30)(A) ("Section 30(A)"). Those arguments are mistaken.

There is no basis for petitioners' contention that a Supremacy Clause challenge is inappropriate in the Section 30(A) context because Congress did not create a separate statutory cause of action "to enforce" Medicaid or confer privately enforceable "individual rights." Pet. Br. 20, 25. The absence of a separate statutory cause of action is of no moment because a plaintiff asserting a cause of action under the Supremacy Clause does not seek to "enforce" the statute. Such a suit does not afford affirmative relief, such as an injunction directing the defendant to take an affirmative act, or retrospective relief, such as damages. Rather, a Supremacy Clause challenge is limited to vindicating the primacy of federal law over inconsistent state law through a declaration that the state law is invalid and an injunction against its enforcement.

The preemptive effect of federal law under the Supremacy Clause does not depend upon Congress having created a cause of action against the state. Congress

need not specify a statute's preemptive effect at all. Indeed, state law can be invalid under the Supremacy Clause even in the absence of congressional legislation. In *American Insurance Ass'n* v. *Garamendi*, 539 U.S. 369 (2003), for example, an executive agreement was held to preempt a California statute purporting to regulate conduct relating to Holocaust-era insurance policies. *Id.* at 419-420. See also *Zschernig* v. *Miller*, 389 U.S. 431, 441 (1968) (state law interfering with foreign policy can be preempted "even in the absence of a treaty"). And a preemptive federal statute may be directed at private parties, or even federal officials, rather than at the state. See, *e.g.*, *Crosby* v. *Nat'l Foreign Trade Council*, 530 U.S. 363, 388 (2000) (statute authorizing President to adopt calibrated sanctions policy against Burmese regime preempted state secondary boycott of companies doing business with Burma). In such circumstances, one would hardly expect Congress to create a private cause of action against the state solely on the off-chance a state enacted legislation to frustrate the federal scheme.

Petitioners' other arguments also fail to justify refusing to recognize a Supremacy Clause cause of action in this case. There is no basis for petitioners' assertion that the Supremacy Clause can only be vindicated by parties who are "regulated" by the invalid state statute. Pet. Br. 43. In *Crosby*, for example, Massachusetts' policy of not contracting with companies doing business in Burma could not be "enforced" against private entities, yet companies that were ineligible to receive state contracts were permitted to bring a Supremacy Clause challenge to the state statute. To the extent that being "regulated" is an essential prerequisite, Medicaid providers are unquestionably at least as regu-

lated as (if not more than) other businesses that have brought successful Supremacy Clause challenges before this Court. Providers thus plainly have a sufficiently direct injury from California's rate cuts to confer standing. Precluding such directly injured parties from bringing a Supremacy Clause challenge would be inconsistent with this Court's recognition that "[a]n individual has a direct interest in objecting to laws that upset the constitutional balance between the National Government and the States when enforcement of those laws causes injury that is concrete, particular, and redressable." *Bond* v. *United States*, 131 S. Ct. 2355, 2364 (2011).

Nor does the fact that Medicaid was enacted under Congress's Spending Clause power diminish its preemptive effect. And, finally, contrary to petitioners' suggestion, Congress has not impliedly precluded a Supremacy Clause cause of action by creating an administrative remedy to enforce Section 30(A) that must be exclusive in order to be effective. Indeed, the administrative process for overseeing state Medicaid programs is structurally incapable of preventing states from violating Section 30(A).

I. SUPREMACY CLAUSE CHALLENGES PLAY A CRITICAL ROLE IN VINDICATING THE PRIMACY OF THE MEDICAID ACT OVER INCONSISTENT STATE LAWS

Congress's purpose in establishing the Medicaid program, codified in Title XIX of the Social Security Act ("SSA"), 42 U.S.C. 1396 *et seq.*, was to provide comprehensive health benefits to "the most needy in the country." *Schweiker* v. *Hogan*, 457 U.S. 569, 590 (1982) (quoting H.R. Rep. No. 213, 89th Cong., 1st

Sess., 66 (1965)). While originally targeting limited subsets of individuals in particularly difficult circumstances, Medicaid was gradually expanded to protect additional populations unable to secure insurance in the private market. Many beneficiaries are unable to work, and those who can are often unable to secure private, employer-sponsored insurance. See Medicaid and CHIP Payment and Access Commission ("MACPAC"), Report to the Congress on Medicaid and CHIP 10 (2011) (the "MACPAC Report"). Today, Medicaid (along with the Children's Health Insurance Program ("CHIP")) provide coverage for 75 million beneficiaries—constituting more than a quarter of the population of the United States and one-third of all children—who otherwise would likely have no health care coverage at all. *Id* at 17, 75. That figure is likely to grow even larger in the future. See, *e.g.*, Affordable Care Act, Pub. L. No. 111-148, 124 Stat. 119 (2010).

Medicaid's beneficiaries rely on the program to guarantee them access to critical medical services, including preventive health checkups, specialist consultations, mental health counseling, and nursing home care. These 68 million people benefit from Medicaid, but only to the extent that it offers meaningful access to health care services.

As the court of appeals concluded—in a holding that this Court declined to review, and that therefore provides the basic premise of this proceeding—California's imposition of indiscriminate reductions of as much as 10 percent to Medicaid rates that were already below many providers' costs was inconsistent with the federal statutory requirements by which Congress sought to ensure adequate access to medical care for Medicaid beneficiaries. Whether Title XIX is con-

strued as establishing procedural requirements or substantive ones, California's across-the-board cuts based purely on state budgetary considerations violated the federal statutory scheme. Indeed, although "the State's own Legislative Analyst warned that the ten percent rate reduction had 'the potential to negatively impact the operation of the Medi-Cal Program and the services provided to beneficiaries by limiting access to providers and services,'" no state official even *considered* what impact the cuts might have on accessibility. *Independent Living Center* v. *Maxwell-Jolly*, 572 F.3d 644, 656 (9th Cir. 2009). Predictably, the cuts did "force[] at least some providers to stop treating Medi-Cal beneficiaries." *Id.* at 657.

A decision in favor of petitioner would allow not only California, but all states, to defy federal law with virtual impunity. Indeed, in the absence of a Supremacy Clause challenge, states will be emboldened to enforce their invalid laws against individuals and businesses who are directly injured thereby. Those injured parties will have no avenue by which to vindicate the supremacy of federal law over inconsistent state policy. Where, as here, the state disregards the requirements of Medicaid, it is the Nation's most vulnerable citizens, including millions of seniors, children, pregnant women and people with disabilities, who will suffer most.

A. Congress Required States To Set Medicaid Payment Rates In A Manner That Would Ensure Adequate Access To Health Care For Medicaid Beneficiaries

While Congress gave states a choice whether to establish a Medicaid program, if a state chooses to do so—and to accept the associated federal financial support—

it must comply with the federal requirements for the program set forth in Title XIX and implementing regulations. For those states that choose to participate in Medicaid, Congress specified those requirements that the state's "plan for medical assistance *must*" satisfy. 42 U.S.C. 1396a(a) (emphasis added).

A central requirement of Title XIX is that each state program offer meaningful medical benefits to its Medicaid beneficiaries. Title XIX lists specific services that any participating state Medicaid program "must" make available to beneficiaries, which include inpatient and outpatient hospital services, laboratory and x-ray services, nursing facility services to beneficiaries aged 21 or older, and physician services. 42 U.S.C. 1396a(a)(10), 1396d(a)(1)-(5), (17), (21). States are prohibited from limiting access to these services unless and until they receive explicit permission from HHS through a waiver. See 42 U.S.C. 1315(a), 1396n.

Congress recognized that meaningful access to these mandated services requires adequate access to health care providers. To assure such access, Congress further required that participating state programs

> must * * * provide such methods and procedures relating to the utilization of, and the payment for, care and services available under the plan * * * to assure that payments are consistent with efficiency, economy, and quality of care and are sufficient to enlist enough providers so that care and services are available under the plan at least to the extent that such care and services are available to the general population in the geographic area.

42 U.S.C. 1396a(a)(30)(A). Section 30(A) reflects Congress's specific and expressed intent to "assure" that "care and services are available" to Medicaid beneficiaries "at least to the extent that such care and services are available to the general population." *Ibid.*

Moreover, Section 30(A) expressly links the statutory requirement of available services to the level of payments that state programs offer providers. Because state programs do not generally provide services directly, Congress required that the state's program ensure that "payments * * * are sufficient to enlist enough providers" to make services available at a level equal to that of the general population. 42 U.S.C. 1396a(a)(30)(A). See also H.R. Rep. No. 101-247, at 2116 (1989) (noting that the expanded Section 30(A) codified a regulatory standard "requiring adequate payment levels").[3]

B. Reduced Payment Rates Threaten The Already Fragile System For Delivering The Level Of Services Mandated By Congress

A Medicaid program's ability to provide adequate access to services as required by Congress depends upon its paying rates that are adequate to attract providers. States generally do not provide Medicaid bene-

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[3] Petitioners cite Congress's repeal of the "Boren Amendment" of Title XIX as evidence that Congress regards private suits challenging the adequacy of Medicaid payments as "antithetical" to States' flexibility in administering Medicaid. Pet. Br. 31. Petitioners are incorrect, as the repeal of the Boren Amendment in 1997 had no implications for suits to vindicate Section 30(A). See Br. of Intervenor Resp. in No. 09-958 and California Pharmacists Resp. in No. 09-1158, at 57-59.

fits directly to program beneficiaries. Instead, states contract with health care providers—physicians, dentists, hospitals, clinics, mental health centers, nursing homes, home health agencies and others—to provide them.

Medicaid payments, however, are often well below the levels needed to sustain an adequate provider network. Hospital and nursing home rates, for example, not only lag behind payments offered by Medicare and commercial payers for similar services, but also fall far short of provider costs. The hospital industry has found Medicaid margins to be on average almost *15 percent lower than hospital costs.* See Milliman, Hospital & Physician Cost Shift: Patient Level Comparison of Medicare, Medicaid, and Commercial Payers 6 (Dec. 2008). Children's hospitals experience an even greater shortfall, with Medicaid on average paying only 77 percent of their costs. National Association of Children's Hospitals and Related Institutions, FY 2009 Annual Survey on Utilization and Financial Indicators of Children's Hospitals (2009). Base payments to public hospitals on average are only 76 percent of hospital costs. And although public hospitals often have access to additional Medicaid payments to support their public missions, over 40 percent still report a loss on providing Medicaid care. National Association of Public Hospitals and Health Systems, America's Public Hospitals and Health Systems, 2009 Results of the Annual NAPH Hospital Characteristics Survey 13-14 (2010). The nursing home industry similarly has found that Medicaid pays only 91 percent of provider costs. See Eljay LLC, A Report on Shortfalls in Medicaid Funding for Nursing Home Care 2 (2010). The same study calculated that, on average, nursing homes lose $17.33 per-

Medicaid patient, per-day. See *ibid.* In other words, most providers lose money for each Medicaid beneficiary that they treat.

Unchecked, and increasingly common, reductions in Medicaid payment rates to institutional providers pose a direct threat to beneficiaries' access to medical services. Many initiatives that would improve beneficiary access to care have gone unimplemented, with hospitals concluding that high Medicaid volumes, coupled with below-cost reimbursement rates, would make these initiatives financially unsustainable. See The Lewin Group, Analysis of Medicaid Reimbursement in Oregon 44-45 (2003). Existing services have, in some cases, been discontinued for the same reason. In one highly publicized case, a hospital in Clare, Michigan, shuttered its obstetrical unit in direct response to the state's inadequate Medicaid payments. See Kevin Sack, *As Medicaid Payments Shrink, Patients are Abandoned*, N.Y. Times, March 15, 2010. The state program reimbursed only 65 percent of hospital costs. *Ibid.*

Lowering payment rates for physicians likewise presents a direct threat to Medicaid beneficiaries' access to such services. Ample evidence, including government reports, demonstrates that low reimbursement rates have led many physicians, and particularly specialists, to stop treating Medicaid patients. For example, while 79 percent of physicians participating in the Medicaid and CHIP accept all privately-insured children as new patients, less than half—only 47 percent—accept all new patients covered by Medicaid or CHIP. See U.S. Government Accountability Office, Medicaid and CHIP: Most Physicians Serve Covered Children but Have Difficulty Referring Them for

Specialty Care, GAO-11-624, at 11 (2011) ("GAO Report"). Even more troubling, another survey found that almost half of office-based physicians had difficultly referring Medicaid patients for specialty consultations, more than three times the rate of difficulty experienced in referring privately insured patients for those same services. See MACPAC Report at 132.

Physicians already cite inadequate payment as the most common reason for not accepting Medicaid patients. MACPAC Report at 132. Among physicians who do not serve Medicaid/CHIP children, 95% cited low reimbursement rates as influencing their decision. See GAO Report at 18; see also Kaiser Commission on Medicaid and the Uninsured, Physician Willingness and Resources to Serve More Medicaid patients: Perspectives from Primary Care Physicians 3 (2011) (noting that almost 90 percent of primary care practitioners who accept no or only some new Medicaid patients cite inadequate reimbursement as a reason for their decision not to participate).

Beyond the direct impact on the availability of physician services, inadequate payment rates for doctors also have the indirect effect of shifting the cost of Medicaid services to hospitals, whose resources are already strained. With shrinking access to office-based specialty care, many Medicaid beneficiaries turn to hospital emergency departments for this care. California HealthCare Foundation, Issue Brief: Overuse of Emergency Departments Among Insured Californians (2006); Peter J. Cunningham & Len M. Nichols, *The Effects of Medicaid Reimbursement on the Access to Care of Medicaid Enrollees: A Community Perspective*, 62 Med. Care Research & Rev. 676, 691 (2005). Because providing services at hospital emergency rooms is more

costly than at doctors' offices,[4] indiscriminately reducing payments to doctors results in a net reduction in efficiency for the Medicaid program.

C. State "Flexibility" In Administering The Medicaid Program Does Not Extend To Reducing Beneficiary Access In Response To Budgetary Shortfalls

Medicaid's federal-state partnership structure offers states significant flexibility in establishing delivery systems, developing payment methodologies, and setting payment rates. While this flexibility is intended to allow states to achieve the "best value" from their Medicaid programs, see 76 Fed. Reg. 26342, 26343 (May 6, 2011), states have instead repeatedly invoked this "flexibility" as an excuse to use Medicaid rate cuts to balance their budgets, resulting in undermining efficiency without improving quality, the two benchmarks by which "value" is generally assessed. See, *e.g.*, U.S. Government Accountability Office, Value in Health Care: Key Information for Policymakers to Assess Efforts to Improve Quality While Reducing Costs, GAO-11-445, at 2 (2011).

Multiple federal courts have found that Section 30(A) prohibits indiscriminate cuts to Medicaid payments in response to budgetary pressure. The Ninth Circuit found that California had failed to consider the potential impact of its 2008 and 2009 Medicaid rate cuts on efficiency, economy, quality, or access to care, and

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[4] See Linda C. Baker & Laurence S. Baker, *Excess Cost of Emergency Department Visits for Nonurgent Care*, 13 Health Affairs 162 (Nov. 1994).

the court therefore set aside the legislation as preempted by Section 30(A). See *Independent Living Center*, 572 F.3d at 652. Other courts have reached similar conclusions. The Eighth Circuit has likewise held that Section 30(A) "mandates consideration of the equal access factors of efficiency, economy, quality of care and access to services in the process of setting or changing payment rates," and that a state therefore cannot make indiscriminate payment cuts based on budgetary grounds alone. *Minn. Homecare Ass'n* v. *Gomez*, 108 F.3d 917, 918 (1997). See also *Amisub (PSL), Inc.* v. *Col. Dep't of Soc. Services*, 879 F.2d 789, 800 (10th Cir. 1989), cert. denied 496 U.S. 935 (1990) ("[B]udgetary constraints cannot excuse noncompliance with federal Medicaid law."); *Kan. Hosp. Ass'n* v. *Whiteman*, 835 F. Supp. 1556, 1570-1571 (D. Kan. 1993) (holding that, where "the significant increase in the co-pay requirement is proposed solely because of its budgetary impact in favor of the state, without considering the other factors listed in the statute, the amendment would appear to violate 42 U.S.C. § 1396a(a)(30)(A)").

D. Absent Supremacy Clause Suits, States Will Continue Making Indiscriminate Rate Cuts, Thus Threatening Medicaid's Ability To Serve Its Congressional Purpose

Although it is well established that Congress prohibited states from simply slashing their rates in an indiscriminate fashion in order to close a budget gap, in the absence of Supremacy Clause challenges, states will remain largely free to do so. The system of federal administrative oversight is simply inadequate to protect the Medicaid Act from such state infringement. Although states must submit plans and any amendments to those plans for approval by the Centers for Medicare

and Medicaid Services ("CMS"), which administers the Medicaid program within HHS, CMS lacks the information necessary to assess the impacts of state plan amendments ("SPAs") on access to care. And the sole federal remedy once a violation is detected—withholding federal funds—is so unpalatable that states can largely ignore the federal administrative process, as petitioners have done here. Supremacy Clause challenges provide an essential mechanism for ensuring that states are not implementing Medicaid policies that are contrary to superior federal law.

1. CMS Lacks The Information That Would Be Necessary To Assess State Compliance With Section 30(A)

No formal processes currently exist by which CMS can assess the adequacy of beneficiary access to Medicaid services. To the extent CMS reviews access at all, it does so informally, in the process of reviewing an SPA. Any review in that context, however, must rely entirely on information submitted by the state, because the SPA approval process affords beneficiaries and providers no meaningful role or redress.

The administrative review process affords CMS little opportunity to gather any reliable information about the extent of beneficiaries' access to health services. While CMS requires that states provide public notice of proposed changes to payment methodologies, states need not solicit or incorporate public comments in response to this notice. 42 C.F.R. 447.205. Once an SPA is submitted, negotiations occur exclusively and privately between CMS and the state, and most disputes between CMS and the state are resolved during these negotiations. Providers have no express opportunity

for input unless CMS *denies* a SPA and the state appeals that denial to the Secretary of HHS. 42 C.F.R. 430.18. At that point, providers can seek to be recognized as parties to the hearing or to participate as amici, 42 C.F.R. 430.76, but the rarity of reconsideration requests renders provider participation virtually nonexistent.[5] Moreover, because SPA reviews relating to payment cuts arise only when a state seeks CMS permission for those cuts, the state lacks any incentive to provide transparent and objective information demonstrating the full impact of those cuts on beneficiaries' access to care.[6]

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[5] Since June 1, 2009, CMS has approved 640 SPAs. Centers for Medicare & Medicaid Services, Medicaid State Plan Amendments, https://www.cms.gov/MedicaidGenInfo/StatePlan/list.asp (accessed July 11, 2011). During that same period, there have only been four requests for reconsideration. 74 Fed. Reg. 29703 (June 23, 2009); 75 Fed. Reg. 80058 (Dec. 21, 2010); 76 Fed. Reg. 34711 (June 14, 2011); 76 Fed. Reg. 44591 (July 26, 2011).

[6] After the Court granted certiorari in these cases, CMS issued proposed regulations to create a process by which states could demonstrate compliance with Section 30(A). 76 Fed. Reg. 26342 (May 6, 2011). These proposed regulations have been widely criticized as representing little improvement over the current SPA approval process. See Sara Rosenbaum, *Medicaid and Access to Health Care – A Proposal for Continued Inaction?*, 365 New Engl. J. Med. 102-104 (July 14, 2011). Regardless of their final form, the new regulations cannot obviate the need for a judicial remedy against state laws that violate the Medicaid Act. CMS cannot, through administrative rulemaking, give itself the power to enjoin state laws that conflict with the Medicaid Act. And, as described below, judicial injunctions against preempted state laws are the *only* effective means of vindicating the supremacy of the Medicaid Act.

2. Federal Injunctive Relief Provides A Necessary Complement To HHS's Enforcement Powers

CMS's enforcement powers are structurally inadequate to ensure state compliance with Section 30(A). To the extent CMS identifies a violation, its sole remedy is the disallowance process. Under this authority, CMS may withhold or limit Medicaid support to that state until the agency is satisfied that the program is and will continue to be compliant. 42 U.S.C. 1396c; 42 C.F.R. 430.35. However, CMS's decision to withhold federal funds, either in part or in full, is fraught with potentially adverse consequences. Such action is counterproductive from a practical perspective; the lack of federal funds would likely leave states unable to pay providers, causing providers to stop treating Medicaid beneficiaries and further exacerbating the access problem. Moreover, CMS almost certainly would be subject to acute political pressure, both from the state itself and its Congressional delegation, should it even threaten to withhold funds. Withholding funds is an extraordinary remedy to be used only in the most extreme instances of non-compliance. It is inappropriate, and likely ineffective, for disputes of a lesser magnitude.

California's 2008 and 2009 payment cuts demonstrate the limitations of HHS's enforcement powers and the essential role played by federal courts in vindicating the requirements of Section 30(A). In September 2008, after these cuts were enacted, they were submitted for CMS approval through the SPA process. See Br. of Intervenor Resp. in No. 09-958 and California Pharmacists Resp. in No. 09-1158, at 6. Within 90 days, CMS informed California that CMS could not approve the cuts because the state had provided inade-

quate information to demonstrate that the cuts would not violate federal Medicaid requirements. *Ibid.* California, however, simply ignored CMS's request for further information. *Ibid.* Finally, on November 18, 2010, over two years after California had implemented its rate cuts, CMS denied the SPAs for lack of adequate information. U.S. Cert. Amicus Br. 7. Throughout this period, while the state was simply ignoring CMS's administrative review, and even after CMS had denied approval of the SPAs, California *persisted* in paying providers at the reduced rate except where the reduced rate was specifically enjoined by the federal courts. Br. of Intervenor Resp. in No. 09-958 and California Pharmacists Resp. in No. 09-1158, at 5. The only cuts that California did not unilaterally implement were those that had been enjoined in actions brought under the Supremacy Clause.

A similar situation recently arose in Indiana, with the state once again ignoring CMS's disapproval of an SPA. The Indiana legislature had passed legislation prohibiting providers that furnish abortion services from participating in the Medicaid program. This provision went into effect on May 10, 2011. Implementing this provision immediately, Indiana then sought CMS approval through the SPA process. CMS disapproved the SPA on June 1, 2011, explaining that the Indiana law violated the Medicaid Act. Despite this disapproval, Indiana continued enforcing the legislation and CMS undertook no enforcement activities. The policy was not reversed until June 24, 2011, when the United States District Court for the Southern District of Indiana enjoined further enforcement. See Entry on Mot. For Prelim. Inj., No. 1:11-cv-630-TWP-TAB (S.D. Ind. June 24, 2011).

As these examples demonstrate, without an available cause of action under the Supremacy Clause, states would be free to adopt and enforce against providers rate cuts that are precluded by federal law.

II. THERE IS NO BASIS TO CONCLUDE THAT A SUPREMACY CLAUSE CHALLENGE IS PARTICULARLY INAPPROPRIATE IN THE MEDICAID CONTEXT

From its earliest cases, this Court has recognized that "plaintiffs may vindicate [statutory] preemption claims by seeking declaratory and equitable relief in the federal district courts through their powers under federal jurisdictional statutes." *Golden State Transit Corp.* v. *City of Los Angeles*, 493 U.S. 103, 119 (1989) (Kennedy, J., dissenting); *id.* at 113-114 (collecting cases so holding). And, as the Solicitor General recognizes, the Court has "decided dozens of preemption claims against state officials on the merits," U.S. Br. 17, on the premise that "[a] plaintiff who seeks injunctive relief from state regulation, on the ground that such regulation is pre-empted by a federal statute which, by virtue of the Supremacy Clause of the Constitution, must prevail, * * * presents a federal question which the federal courts have jurisdiction under 28 U.S.C. § 1331 to resolve." *Shaw* v. *Delta Air Lines, Inc.*, 463 U.S. 85, 96 n.14 (1983). Implicitly acknowledging the strength of that precedent, much of petitioners' brief, like that of the Solicitor General, assumes the availability of a cause of action under the Supremacy Clause in most circumstances, and instead argues that such a cause of action should not be recognized in the specific context of a suit to set aside a state law that is invalid because it conflicts with Section 30(A).

There is no basis, however, for petitioners' contention that a Supremacy Clause challenge is particularly inappropriate in the Medicaid context generally, or the Section 30(A) context specifically. Petitioners' argument that Congress did not create a statutory cause of action to enforce Medicaid is inapposite. Unlike a statutory cause of action or one under Section 1983, a cause of action under the Supremacy Clause does not allow a plaintiff to seek retrospective or affirmative relief, such as damages or an injunction directing the defendant to take some affirmative action. Rather, relief is limited to a declaration that the state law is invalid and an injunction against its enforcement. Moreover, the Supremacy Clause renders invalid state statutes that conflict with federal law even in circumstances where Congress would not be expected to have created a cause of action against the state. For example, state laws can be preempted even in the absence of any federal statute, or where the federal legislation, if there is any, is directed at private parties, or even federal officials, rather than at the state.

Nor do petitioners' other arguments justify refusing to recognize a Supremacy Clause cause of action in this case. This Courts' cases do not support petitioners' contention that the Supremacy Clause can only be vindicated by parties who are "regulated" by the invalid state statute. Pet. Br. 43. But, if being regulated is a necessary prerequisite, Medicaid providers are easily as regulated as other businesses that have successfully brought Supremacy Clause challenges before this Court. Nor does the fact that Medicaid was enacted under Congress's Spending Clause power diminish its preemptive effect. And, finally, contrary to petitioners' suggestion, the administrative review process for state

plans does not reflect a congressional intent to preclude other remedies against state laws that violate Section 30(A).

A. The Availability Of A Supremacy Clause Challenge Does Not Depend On Whether The Medicaid Act Creates A Cause Of Action Or An Individually Enforceable Right

While petitioners expend numerous pages seeking to prove that Congress did not provide for a statutory cause of action in the Medicaid Act itself (Pet. Br. 20-26), that question is beside the point. This Court has consistently held that "the existence of conflict cognizable under the Supremacy Clause does not depend on express congressional recognition that federal and state law may conflict." *Crosby* v. *Nat'l Foreign Trade Council*, 530 U.S. 363, 388 (2000). No statutory cause of action is necessary because the foundational decision in *Ex parte Young*, 209 U.S. 123 (1908), established the authority of federal courts to "vindicate federal rights and hold state officials responsible to 'the supreme authority of the United States.'" *Pennhurst State School & Hosp.* v. *Halderman*, 465 U.S. 89, 105 (1984). See *Alden* v. *Maine*, 527 U.S. 706, 755, 757 (1999).

In *Shaw*, for example, the Court upheld the federal courts' authority to grant the plaintiff relief in a Supremacy Clause challenge, despite the absence of a cause of action derived from the preemptive federal statute. The Court noted that it "frequently has resolved pre-emption disputes in a similar jurisdictional posture." 463 U.S. at 96 n.14. More recently, in *Verizon Maryland, Inc.* v. *Pub. Serv. Comm'n of Maryland*, 535 U.S. 635 (2002), the Court rejected the assertion that a district court could not reach the merits of a

preemption claim unless the plaintiff had demonstrated a statutory cause of action.

Petitioners' suggestion (Pet. Br. 33) that recognition of a Supremacy Clause cause of action would permit an "end-run" around *Alexander* v. *Sandoval*, 532 U.S. 275 (2001), and *Cort* v. *Ash*, 422 U.S. 66 (1975), is mistaken. Petitioners' arguments ignore the critical distinctions between a cause of action for affirmative relief to enforce a federal right, and a suit challenging a state statute under the Supremacy Clause, which merely asks the court to set aside and enjoin enforcement of the invalid state law. "[T]he availability of prospective relief of the sort awarded in *Ex parte Young* gives life to the Supremacy Clause. Remedies designed to end a continuing violation of federal law are necessary to vindicate the federal interest in assuring the supremacy of that law." *Green* v. *Mansour*, 474 U.S. 64, 68 (1985). Indeed, in several decisions in which the Court has held a damages remedy unavailable against a state, the Court has stressed that denying a damages remedy "strikes the proper balance between the supremacy of federal law and the separate sovereignty of the States" precisely because *Ex parte Young* and similar "[e]stablished rules provide ample means to correct ongoing violations of law and to vindicate the interests which animate the Supremacy Clause." *Alden*, 527 U.S. at 757. Here, by contrast, if respondents are denied a cause of action under the Supremacy Clause, there will be no effective "means to vindicate" the primacy of federal law over a conflicting state statute.

Petitioners' focus on the purported absence of a statutory "right" under Medicaid enforceable under Section 1983 is similarly misplaced. "[Section] 1983 does not provide the exclusive relief that the federal

courts have to offer." *Golden State Transit Corp.*, 493 U.S. at 119 (Kennedy, J., dissenting). Indeed, this Court has consistently upheld Supremacy Clause challenges without relying on either Section 1983, or the preemptive federal statute to establish a cause of action. See, *e.g.*, *Crosby*, 530 U.S. at 363; *United States* v. *Locke*, 529 U.S. 89 (2000); *Gade* v. *Nat'l Solid Waste mgmt. Ass'n*, 505 U.S. 88 (1992); *Lawrence County* v. *Lead-Deadwood Sch. Dist.*, 469 U.S. 256 (1985); *Capital Cities* v. *Crisp*, 467 U.S. 691 (1984).[7]

In the Medicaid context itself, the Court has addressed preemption claims in numerous cases in which there was no individually enforceable right or statutory cause of action. In *Pharm. Research & Mfrs. of Am.* v. *Walsh*, for example, an association of drug manufacturers challenged the constitutionality of Maine's prescription drug rebate program. 538 U.S. 644, 650 (2003). All seven Justices agreed that the Supremacy Clause provided a preemption claim to challenge a state law as

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[7] The Solicitor General's brief discusses two cases that it claims demonstrate that "the Court clearly viewed Section 1983 as the sole source of a private right of action to enforce statutory provisions governing joint federal-state programs under the SSA." U.S. Br. 29-30 (discussing *Maine* v. *Thiboutot*, 448 U.S. 1 (1980) and *Suter* v. *Artist M.*, 503 U.S. 347 (1992)). In each of those cases, however, the plaintiffs sought affirmative relief that could not have been provided by a cause of action under the Supremacy Clause alone. See *Suter*, 503 U.S. at 353 (noting district court's "injunction requiring petitioners to assign a caseworker to each child placed in DCFS custody within three working days of the time the case is first heard in Juvenile Court"); *Thiboutot*, 448 U.S. at 3 (noting that the Superior Court had "ordered [petitioners] to adopt new regulations * * * and to pay the correct amounts retroactively to respondents").

invalid under the Medicaid Act. *Id.* at 667-668. See also *Ark. Dep't. of Health & Human Servs.* v. *Ahlborn*, 547 U.S. 268, 274, 292 (2006) (Medicaid Act preempted ADHS' assertion of a claim against proceeds that a beneficiary received from a personal injury settlement).

Petitioners' argument that a Supremacy Clause challenge is unavailable whenever Congress has failed to provide a statutory cause of action or "right" is particularly misplaced in light of the fact that state law can be preempted under the Supremacy Clause even in the absence of federal legislation. In *American Insurance Ass'n* v. *Garamendi*, for example, the Court upheld a Supremacy Clause challenge based on conflict between a state law and federal foreign policy reflected in Executive Agreements. 539 U.S. 396, 419-420 (2003). See also *Zschernig* v. *Miller*, 389 U.S. 431, 441 (1968) (holding that "[w]here [state] laws conflict with a treaty, they must bow to the superior federal policy. Yet, even in the absence of a treaty, a State's policy may disturb foreign relations."). Because federal "law" that is not enacted by Congress can preempt inconsistent state policy, it would be incongruous to require a congressionally enacted private right of action in order to vindicate that preemptive federal policy.

Even where Congress has itself enacted the preemptive law in question, it may have had no occasion to consider whether to create a cause of action to challenge a conflicting state law. In *Crosby*, for example, the preemptive statute at issue authorized the President to impose sanctions on the Burmese regime. 530 U.S. at 366. The statute disavowed creation of any individual rights, and it did not provide a cause of action against anyone, much less against a state in the unexpected event that one might adopt its own conflict-

ing Burma sanctions policy. See Omnibus Consolidated Appropriations Act, Pub. L. No. 104-208, § 570, 110 Stat. 3009 (1996); Exec. Order No. 13,047, § 7, 62 Fed. Reg. 28,301 (May 20, 1997) ("Nothing contained in this order shall create any right or benefit, substantive or procedural, enforceable by any party against the United States * * * or any other person."); 31 C.F.R. pt. 537 (2003). This Court granted prospective injunctive relief notwithstanding the absence of a statutory right or cause of action. Congress undoubtedly intends that state government officers may not systematically violate federal statutes, even ones that do not directly regulate states. By recognizing an implied cause of action under the Supremacy Clause in *Crosby*, the Court gave effect to that congressional intent, and vindicated the structural federalism that is fundamental to constitutional design. See *Bond v. United States*, 131 S. Ct. 2355, 2364 (2011) ("An individual has a direct interest in objecting to laws that upset the constitutional balance between the National Government and the States when enforcement of those laws causes injury that is concrete, particular, and redressable.").

Significantly, pursuant to the Supremacy Clause, federal legislation may constrain a state in ways that private actors are not. In *Crosby*, for example, the federal Burma sanctions act did not preclude a private individual or corporation from engaging in a secondary boycott of companies that did business with Burma. But, under the Supremacy Clause, *a state* was foreclosed from adopting such a sanctions policy because it undermined the President's capacity for diplomacy, which was central to the federal sanctions legislation. Conversely, a federal statute that regulates automobile manufacturers may have no direct application to states

at all, but nonetheless constrains a state from adopting legislation that conflicts with the federal standard. Thus, asking whether the statute provides a statutory cause of action to enforce its mandate tells one little, if anything, about whether Congress intended that a cause of action be available to set aside a state law that conflicts with the federal policy. In short, a statutory cause of action to enforce the statute's requirements through affirmative relief is distinct from a cause of action under the Supremacy Clause to set aside an inconsistent state law. The availability, or absence, of the former type of action is inapposite to the availability of the latter.

B. A Supremacy Clause Cause Of Action Is Not Limited To Parties Who Are "Regulated" By The Invalid State Statute, But If It Were, Medicaid Providers Would Qualify

Apparently recognizing that they cannot explain this Court's Supremacy Clause precedent by reference to statutes that provided statutory rights or causes of action, petitioners urge that the remaining cases merely represent instances in which a regulated party that might otherwise have raised preemption as a defense to an enforcement action was permitted to bring an anticipatory claim for declaratory relief. Pet. Br. 43. That explanation also fails to account for the full breadth of the Court's preemption precedent. But, to the extent petitioners' definition of "regulated" parties is broad enough to encompass the remaining precedent, Medicaid providers would easily so qualify.

Notably, petitioners appear to recognize that their framework cannot explain the Court's decision in *Crosby*, and so petitioners ignore the case. The Solicitor

General readily acknowledges that *Crosby* does not "readily" fit petitioners' artificially constructed category. U.S. Br. 23 n.8. The government contends, however, that *Crosby* is sufficiently analogous to the anticipatory assertion of a defense against enforcement because "the state law was an affirmative (and independent) exercise of the State's authority to impose and enforce what were essentially state regulatory standards." *Ibid.* But that is not accurate. In *Crosby*, Massachusetts had adopted a law prohibiting state contracting officers from purchasing goods from companies that did business with Burma. 530 U.S. at 367-370. There were no "enforcement" proceedings that could be brought against such companies; they were simply ineligible for government contracts.[8]

Even assuming that it is necessary to be a "regulated" entity in order to maintain a Supremacy Clause challenge, Medicaid providers are easily as "regulated" by a State's Medicaid payment rates as were the business plaintiffs in *Crosby*. Medicaid providers are paid directly by Medicaid for the services they provide to eligible beneficiaries, and, significantly, these payments must be accepted as payments in full. See Cal. Welf. & Inst. Code § 14019.4(a) & (c); see also 42 U.S.C. 1320a-7b(d); 42 C.F.R. 447.15; *Rehab. Ass'n of Va.* v. *Kozlowski*, 42 F.3d 1444, 1447 (4th Cir. 1994), cert. denied 516 U.S. 811 (1995). Moreover, although providers, like

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[8] Ironically, the Solicitor General's position here would defeat its ongoing challenge to Arizona's immigration law, SB 1070. *United States* v. *Arizona*, 641 F.3d 339 (9th Cir. 2011). The federal government is not subject to enforcement under the law, and, moreover, portions of Arizona's immigration statute directly regulate only state officials. See, *e.g.*, A.R.S. § 11-1051.

states, "opt in" to Medicaid, non-participation is virtually impossible as a matter of practical necessity. Providers who choose not to participate in Medicaid face significant potential consequences. For instance, the Emergency Medical Treatment and Active Labor Act ("EMTALA"), 42 U.S.C. 1395dd *et seq.*, requires hospitals with emergency departments to treat Medicaid beneficiaries who present themselves to those emergency departments. Violations of EMTALA carry significant civil penalties; see also Bradley J. Sayles, *Preemption or Bust: A Review of Recent Trends in Medicaid Preemption Actions*, 27 J. Contemp. Health L. & Pol'y 120, 123-124 (2011). Medicaid providers are, thus, at least as directly affected by a state's across-the-board cut in payment rates as were the businesses in *Crosby*, which simply wanted to be able to bid for more work from Massachusetts. To the extent that Supremacy Clause challenges are limited to "regulated" entities, respondents certainly qualify under the criteria applied in *Crosby*.

The "regulated party" test, as construed by the Solicitor General, really amounts to a proxy for the kind of direct injury that would give a party standing. See *Bond*, 131 S. Ct. at 2363-2365 (holding that individuals with concrete injury have "standing to object to a violation of a constitutional principle that allocates power within government"). Here, there is no doubt that respondents and the patients they treat would be directly injured if California were permitted to implement its illegal rate cuts, and their Supremacy Clause challenge is therefore proper.

C. There Is No Basis For According Spending Clause Legislation Less Effect Under The Supremacy Clause

Nothing in the text of the Constitution limits the preemptive effect of a law depending upon the constitutional power Congress was exercising in adopting the statute. The preemptive effect under the Supremacy Clause of statutes enacted under the Spending Clause is the same as for laws enacted under any other constitutional power. Like all statutes, laws enacted under the Spending Clause are "supreme" over inconsistent state law.

Thus, this Court has repeatedly recognized the preemptive power of Spending Clause legislation, including Medicaid in particular, over conflicting state statutes. See, *e.g.*, *Dalton* v. *Little Rock Family Planning Servs.*, 516 U.S. 474, 476-478 (1996) (per curiam) (leaving in place district court injunction enjoining application of state law prohibiting expenditure of state funds for abortions in the case of incest or rape to the extent it "imposed obligations inconsistent with" the Hyde Amendment to the Medicaid Act, a spending bill); *Blum* v. *Bacon*, 457 U.S. 132, 145-146 (1982) (state program discriminating against AFDC beneficiaries preempted by federal regulation); *Carleson* v. *Remillard*, 406 U.S. 598, 604 (1972) (state rule denying assistance to children of military members preempted by AFDC); *cf. Pennsylvania Prot. & Advocacy, Inc.* v. *Houstoun*, 228 F.3d 423, 428 (3d Cir. 2000) (Alito, J.). Similarly, in *Townsend* v. *Swank*, 404 U.S. 282, 285 (1971), this Court held that an Illinois statute was "invalid under the Supremacy Clause" because it conflicted with the Aid to Families with Dependent Children program, a provision of the Social Security Act that

was adopted as Spending Clause legislation. See also *Ark. Dep't of Health & Human Servs.*, 547 U.S. at 268.

D. Congress Did Not Adopt An Exclusive Administrative System To Enforce Section 30(A) That Would Preclude Challenges Under The Supremacy Clause

Petitioners contend that permitting a cause of action under the Supremacy Clause is incompatible with "Congress's decision to centralize enforcement authority in HHS." Pet. Br. 26. There is nothing in Medicaid's administrative scheme, however, to suggest that Congress viewed private suits to set aside preempted state statutes as inconsistent with that scheme. Indeed, the Solicitor General disavows any suggestion that "Congress has displayed an intent" to preclude Supremacy Clause challenges. *See* U.S. Br. 32 n.12 (internal quotation omitted). The most the Solicitor General can say is that Section 30(A) would not be "a 'dead letter'" if Supremacy Clause challenges were not permitted. *Ibid.* But that is insufficient to support petitioners' argument for administrative exclusivity.

Petitioners cite this Court's decision in *Astra USA, Inc.* v. *Santa Clara County*, 131 S. Ct. 1342 (2011), in support of their argument, but that case is readily distinguishable. See Br. of Intervenor Resp. in No. 09-958 and California Pharmacists Resp. in No. 09-1158, at 41-42. In particular, the 340B program stands in stark contrast to Section 30(A). In *Astra*, participating pharmaceutical manufacturers each signed a *standard-form* Pharmaceutical Pricing Agreement ("PPA") with HHS. 42 U.S.C. 256b(a). The PPA specifies the maximum price at which manufacturers may sell their drugs to eligible providers, with this price being determined

using a uniform statutory formula. The Medicaid Act, by contrast, is almost unique in its lack of uniformity across the Nation. State Medicaid programs differ significantly from one another. The Medicaid Act permits states to develop unique benefit structures, delivery systems, and payment methodologies. Such a structure does not allow for enforcement under a single nationwide standard.

As previously discussed, *see supra*, 16-21, the administrative system for monitoring compliance with Section 30(A) is particularly lacking. The agency relies on the submission of state plan amendments as the only opportunity to assess rate cuts, and, even then, the agency is entirely dependent on the information submitted by the state. Even when the state ignores the administrative process, it is free to move ahead with its rate cuts with seeming impunity. That is hardly the type of "centraliz[ed] enforcement authority" that would preclude other available means of preventing states from enforcing laws that were contrary to Medicaid's mandates.

CONCLUSION

The Court should affirm the holding of the court of appeals.

Respectfully submitted.

DOUGLAS HALLWARD-DRIEMEIER
Counsel of Record
LARRY S. GAGE
BARBARA D. EYMAN
CHARLES A. LUBAND
DAVID Z. GROSS
MATTHEW B. ARNOULD
ROPES & GRAY LLP

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